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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				
EXAMINER				
SHAFFER, RICHARD R				
ART UNIT		PAPER NUMBER		
3733				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,911

Applicant(s)

SGIER ET AL.

Examiner

Richard Shaffer

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
4a) Of the above claim(s) 25-35 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/CIS)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Election/Restrictions

Newly submitted claims 25-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- I. Claims 1-24, drawn to an apparatus, classified in class 606, subclass 266.
- II. Claims 25-35, drawn to a method, classified in class 606, subclass 279.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the device can be used in a materially different process such as rods along ceilings for lighting.

Since applicant has received an action on the merits for the originally presented invention (**Invention I**), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 recites the limitation "the aperture of the cap has a **spherical** cross-section ..." The aperture as disclosed in the specification as originally filed refers to element 17 which is defined as conical, not spherical. For examination purposes, it is assumed that applicant meant to define the lateral undercuts (18) of the cap as being spherical.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-16 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (US 5,368,594) in view of Vignaud et al (US Patent 5,176,680) and in further view of Schlapfer et al (US Patent 5,501,684).

Martin et al disclose a vertebral arthrodesis device (**Figures 1-4**) comprising: at least two pins (**3**); screws (**5b**) having a head with a cavity (**11**) to receive a pin (**3**); the head having two lateral threaded holes receiving two threaded fastening screws (**14**); a cap (**12**) configured to contact and secure the rod with the cavity (**11**) due to inwardly

inclined side walls (12a); the cap (12) has a conical shape (see **Figure 4** with the inwardly tapered top portion consistent with **element 17 of applicant's device** as shown in **Figures 2 and 3**); the cavity (11) snapping onto the pin (5, **See Column 1, Line 63 through Column 2, Line 13 and Column 3, Line 63 through Column 4, Line 6 discussing "clipping the rods into the cavities prior to applying caps 12**"); and the cavity is able to perpendicular flex (relative to the longitudinal axis of the arthrodesis device) because of two inward pointing slots (13, **Figure 2**).

Martin et al fail to disclose spherical lateral undercuts to allow pivoting, a ring placed along the pin and a spherical cavity capable of securing the pin (spinal rod) with a ring about it. Vignaud et al teaches a similar device with a bone-anchoring portion (1), a split ring (9) slidable along the length of the spinal rod (6), clamping means (7, 8, and 18), spherical cavity (as seen in **Figure 2**), and spherical (are rounded) lateral undercuts (**Figures 1 and 3**, the areas of parts 5 and 17). The ring and lateral undercuts allow for pivoting of the spinal rod as shown in **Figure 2**. It is explained (**Column 1, Lines 1-20**) that fixed systems only allow rods to be placed perpendicular to pedicle screws and thus make it difficult to re-establish physiological curves of the spine. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Martin et al with the split ring and lateral undercuts of Vignaud to allow for placement of a rod in an orientation other than perpendicular to the pedicle screw in order to facilitate the positioning of the spine.

Schlapfer et al teaches in **Figure 2** a sliding ring to allow pivoting of the screw in a bone fixation device longitudinal cuts none of which go through entirely, but initiate at

alternating ends of the ring. This allows greater flexibility of the ring while maintaining integrity. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the split ring in the combination of Martin et al and Vignaud et al with the teaching of Schlapfer et al to allow greater flexibility of the spinal rod while maintaining integrity.

Claims 1-11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al in view of Vignaud et al in further view of Schlapfer et al and in further view of Petreto (US Patent 5,938,663).

The combination of Martin et al, Vignaud et al and Schlapfer et al disclose and teach all of the claimed limitations except for the cavity allowing for angular adjustments of the pin(s) in multiple planes prior to immobilization.

Petreto teaches (**Figure 2; Column 1, Line 8 through Column 2, Line 5**) a device which allows orientation of the pin in all directions (multiple planes) by allowing clearance in all directions about the rod, not only vertically as shown in Vignaud et al. It would have been obvious to one having ordinary skill in the art to design the combination of Martin et al, Vignaud et al and Schlapfer et al with the ability to allow other planes of angulation as a matter of mere substitution for the single planar angulation taught by Vignaud et al with predictable results.

Response to Arguments

Applicant's arguments filed on May 20th, 2008 have been fully considered but they are not persuasive.

In regard to applicant's arguments of the rejection of claim 23 under 35 U.S.C. 112, 1st paragraph, the citation of Figure 1 does not show a spherical cross-section of an aperture as claimed. Claim 23 is dependant upon claim 12 which recites, "at least one cap having an aperture configured to contact and secure the at least one ring within the cavity." Therefore, as shown in Figures 2 and 3, the aperture being referred is that of element 17, not 18 as applicant is attempting to point out in Figure 1. Further, it is improper to refer to a cross-section being spherical whereas a sphere would have a "circular" cross-section.

In regard to applicant's arguments regarding the 35 U.S.C. 103(a) rejection, stating that the combination of Martin et al, Vignaud et al, and Schlapfer et al fail to disclose and/or teach "achieving snap-on installation of the pin on the screw using a spherical ring." Martin et al disclose a snap-on feature, Vignaud et al teach the importance of using a ring within a spherical cavity along with lateral undercuts to allow for angular displacement in multiple planes, and Schlapfer et al teach an improved ball ring also placed within a spherical cavity. As has been stated previously and repeated now, one of ordinary skill in the art using the references of Martin et al and Vignaud et al would have conceived of a snap-on installation with the use of a spherical cavity with undercuts with which a ball ring about a rod would be installed allowing for angular displacement in multiple planes. There

Conclusion

Applicant's amendments stating the cavity allows angulation in multiple planes necessitated the new ground(s) of rejection presented in this Office action. Accordingly,

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733